K010705

PTW-New York Corporation
201 Park Ave., Hicksville, New York 11801
(P) 1-516-827-3181
(F) 1-516-827-3184

MAR 11 2003

510(k) Premarket Notification for PTW OPTIDOS, T10013 Precision Dosemeter for Quality Assurance Measurements in Intravascular Brachytherapy

Manufacturer's 510(k) Summary Certification, 21 CFR 807.92(h):

1. **Company:**

PTW-New York Corporation
201Park Avenue
Hicksville, New York 11801
(P) 1-516-827-3181
(F) 1-516-827-3184

Contact:

Stephen R. Szeglin
General Manager
PTW-New York Corporation
(P) 1-516-827-3181
(F) 1-516-827-3184

Date of Submission:
March 7, 2001

2. **Trade/Proprietary Name:**
PTW OPTIDOS, T10013

Common/Usual Name:
Intravascular Brachytherapy Isotope Calibrator, or
Brachytherapy Isotope Calibrator

3. **Predicate Device(s):**
Victoreen 34-070 Brachytherapy Isotope Calibrator, K931657.

4. **Description of Device(s):**
OPTIDOS is an intravascular brachytherapy isotope calibrator with a scintillation detection system. This dosimetry system is essentially a PTW-UNIDOS electrometer, K951764, with a dedicated photo-sensor input for a scintillation detector. This system was designed in response to numerous requests from the Medical Physics community to provide a highly accurate and precise dosemeter to verify the source strength of beta sources that are now being used in intravascular brachytherapy. It was felt that existing technology, like the predicate device, did not have the accuracy or precision to provide adequate information regarding intravascular brachytherapy beta source strength verification.

Opdid

K010705

PTW-New York Corporation
201 Park Ave., Hicksville, New York 11801
(P) 1-516-827-3181
(F) 1-516-827-3184

510(k) Premarket Notification for PTW OPTIDOS, T10013 Precision Dosemeter for Quality Assurance Measurements in Intravascular Brachytherapy

Manufacturer's 510(k) Summary Certification, 21 CFR 807.92(h) (con't):

5. **Statement of Intended Use:**

OPTIDOS is a brachytherapy isotope calibrator with a scintillation detector. This dosimetry system is designed to perform quality control verification measurements on beta emitting catheter based intravascular brachytherapy sources. OPTIDOS can verify dose rates in water equivalent plastic at a distance of 2 mm and perform verification measurements, beta sources only, as described in the American Association of Physicists in Medicine (AAPM) Task Group 60 report.

6. **Comparison of Technological Characteristics to the Predicate Devices:**

The intended use of OPTIDOS is the same as the Victoreen 34-070 Brachytherapy Isotope Calibrator K931657, the predicate device.

The technological specifications of OPTIDOS meets or exceeds that of the predicate device.

Safety and effectiveness between OPTIDOS and the predicate device is not an issue since OPTIDOS meets or exceeds all of the applicable requirements of:

IEC 60731: Medical Electrical Equipment, Dosimeters with ionization chambers used in radiation therapy (applies to the electrometer portion of OPTIDOS only),
IEC 601-1: Medical Electrical Equipment,
IEC 60601-1-2: Electromagnetic Emissions,
IEC1010 / EN61010: Safety Standard,
IEC 1187 / EN61187: Documentation and content that must accompany the device.

The manufacturing and testing, process and procedures of OPTIDOS exceeds that of the predicates since OPTIDOS meets or exceed ISO 90001 standards.

OPTIDOS will be manufactured in compliance with our ISO 90001 certification and will be CE marked with CE 0124, the predicate device is not CE marked.

It is our opinion that the indications for use, design, materials, manufacturing, and specifications of the PTW OPTIDOS, T10013 do not raise any issues with regard to safety and effectiveness. Hence, PTW considers the T10013 OPTIDOS to be substantially equivalent to the predicate device.

Note: Any statement made in conjunction with this Summary regarding substantial equivalence to another product was made in relation to the 510(k) premarket approval process and should not be interpreted as an admission or used as evidence in patient infringement litigation.

Opdid

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2003

Mr. Stephen R. Szeglin
General Manager
PTW-New York Corporation
201 Park Avenue
HICKSVILLE NY 11801

Re: K010705
Trade/Device Name: PTW OPTIDOS, T10013
Regulation Number: 21 CFR §892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: 90 KXK
Dated: December 9, 2002
Received: December 11, 2002

Dear Mr. Szeglin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K010705

Device Name: PTW OPTIDOS, T10013

Indications For Use:

OPTIDOS is a brachytherapy isotope calibrator with a scintillation detector. This dosimetry system is designed to perform quality assurance measurements on catheter based intravascular brachytherapy sources. OPTIDOS is ideally suited for measuring source strengths of beta emitters, dose rates in water at distances as close as 2 mm, depth dose data, the longitudinal and rotational homogeneity of line sources, and can easily perform all of the quality assurance measurements described in the American Association of Physicists in Medicine (AAPM) Task Group 60 report. Additionally, OPTIDOS can be used for dosimetry measurements on eye plaques that contain radioactive sources. OPTIDOS is a laboratory device and is not designed to come into patient contact.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David B. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K010705

Prescription Use ✓

(Optional Format 3-10-98)

Optic